FEB 1 5 2001

Endoscopy Division

Smith & Nephew, Inc.
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Smith+Nephew

K 003572

510(k) Summary
Dyonics Control RF System
Date Prepared: November 17, 2000

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith + Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810

B. Company Contact

Mark Kieras
Regulatory Affairs Specialist

C. Device Name

Trade Name:	Dyonics Control RF System
Common Name:	Arthroscopic Electrosurgical System
Classification Name:	Arthroscopes & Accessories, Device, electrosurgical, cutting & coagulation & accessories

D. Predicate Devices

Mitek VAPR electrosurgery devices, K974022
Snith & Nephew RF Arthroscopic Wand System K001226

E. Description of Device

The proposed Dyonics Control RF System consists of two components:

3) the Dyonics Series 7000 Arthroscopic Probe, a combined electrical connector, interconnecting cable, handle and wand (handle/wand portion), and
4) the Dyonics Control RF Generator

The RF device is a bipolar device designed for the resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue under a conductive fluid field (0.9% saline, Ringer's lactate, etc.). As such, a dispersive return pad is not required for operation of this device.

D. Intended Use

The Dyonics Series 7000 RF Arthroscopic Probe, when used in conjunction with the Dyonics Control RF Generator Adaptor or Dyonics Control RF generator, is intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels, and coagulation of soft tissue in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow, wrist, and hip

E. Comparison of Technological Characteristics

The Dyonics Control RF System is substantially equivalent in design, materials of contstruction, function and intended use to the following devices cleared for commercial distribution: Mitek VAPR electrosurgery devices and the Smith & Nephew RF Arthroscopic Wand System.

Mark Kieras
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2001

Mr. Mark Kieras
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, Massachusetts 01810

Re: K003572
Trade Name: Dyonics Control RF System
Regulatory Class: II
Product Code: HRX
Dated: November 17, 2000
Received: November 20, 2000

Dear Mr. Kieras:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : ~~K000000~~ K003572

Device Name : Dyonics Control RF System

Indications for Use :

The Dyonics Series 7000 RF Arthroscopic Probe, when used in conjunction with the Dyonics Control RF Generator Adaptor or Dyonics Control RF generator, is intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels, and coagulation of soft tissue in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow, wrist, and hip

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter ____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K003572

Nonrestrictive examples of arthroscopic surgery include:

Knee

Meniscectomy
Lateral Release
Chondroplasty
Synovectomy
ACL Debridement
Plica Removal
Meniscal Cystectomy

Ankle

Fracture Debridement
Excision of Scar Tissue
Synovectomy
Chondroplasty

Wrist

Synovectomy
Cartilage Debridement
Fracture Debridement

Shoulder

Labral Tear Resection
Synovectomy
Excision of Scar Tissue
Acromioplasty
Bursectomy
Subacromial Decompression
Chondroplasty

Elbow

Synovectomy
Tendon Debridement
Chondroplasty